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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/400,365 09/20/99 CHARBEL F 76461

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| EXAMINER |
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TM02/0425

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| CHOI, K | |
| ART UNIT | PAPER NUMBER |

2163
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/400,365

Applicant(s)

CHARBEL ET AL.

Examiner

Kyle J. Choi

Art Unit

2163

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 7.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. The following is a Final Office Action in response to communication received on February 1, 2001. Claims 1, 7, 12, 18, 23, 29, 35, 40, 45, 50 have been amended. In particular, applicant submitted Substitute Amendment A on February 1, 2001 requesting that the prior amendment submitted on October 10, 2000 be canceled *in toto*. Examiner notes that the canceled amendment of October 10, 2000 included a new claim 51, but since the amendment was canceled *in toto* and since the substitute amendment did not have a new claim 51, the present application currently has claims 1-50 pending.

Information Disclosure Statement

2. The Information Disclosure Statements received October 10, 2000 (paper no. 3) and January 8, 2001 (paper no. 7) have been considered. An initialed copy of the Form 1449 is enclosed herewith. Those references crossed out have not been considered because the publishing date (or the lack thereof) renders these references invalid as prior art.

Furthermore, IDS (paper no. 3) was submitted after the first Office Action mailed June 8, 2000 (paper no. 2) without a certification or a filing fee. Since applicant has authorized

any fees due to a deposit account, a fee of \$180.00 have been charged to the deposit account to consider IDS #3. Applicant may disregard the notice indicated in the Non-Responsive communication (paper no. 6) indicating a charge of \$240.00 since the Office inadvertently did not charge that amount at the time the Non-Responsive communication was mailed. The correct fee of \$180.00 is charged from the date of mailing of this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7, 9-11, 18, 20-22, 35, 37-39, 45, 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 7, 18, 35, 45 all recite "the boundary" for which there is no antecedent basis.

6. Claims 9-11, 20-22, 37-39, 47-49 all recite "the cerebral flow" for which there is no antecedent basis. Additionally, all reference to "cerebrum" were deleted from the independent claims by the previous amendment.

Statutory Double Patenting

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claims 2, 13, 24, 30 are provisionally rejected under 35 U.S.C. 101 as claiming the **same invention** as that of claims 2, 9-11, 13, 20-22, 30, 37-39, 47-49 of copending parent U.S. Application No. 09/243,870. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

In particular, independent claims 1, 12, 23, and 29 from which the above-identified claims depend have been amended to

recite "an arterial circulatory network" whereas the corresponding claims in the copending application have been amended to recite "an arterial circulatory network for a cerebrum". However, the above-identified claims recite developing the arterial circulatory network model based on the "Circle of Willis". It is common knowledge in the art that "Circle or Willis" refers for to a specific arterial circulatory network configuration that is only in the brain. Hence, the above-identified claims are reciting exactly the same invention as the corresponding claims in the copending application even though the independent claims of the present invention have been amended to recite a general arterial circulatory network.

Non-Statutory Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 9-11, 20-22, 37-39, 47-49 are provisionally rejected under the judicially created doctrine of double patenting over claims 9-11, 20-22, 37-39, 47-49 of copending parent U.S. Application No. 09/243,870. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The above-indicated claims are dependent on amended independent claims 1, 12, 29, and 40, respectively. In particular, the independent claims have been amended to recite "an arterial circulatory network" whereas the corresponding independent claims in the copending application recite "an arterial circulatory network for a cerebrum". However, the above-identified claims still recite "calculating the cerebral

flow" - i.e., an arterial circulation network in a cerebrum. Hence, the recitation in the above-identified claims are identical to those corresponding claims in the copending application.

The only reason this rejection is "non-statutory double patenting" is because claims 5, 16, 33, and 43 from which claims 9-11, 20-22, 37-39, 47-49 depend, respectively, recite "localizing the corresponding vessel in three-dimensional space" whereas the corresponding claims in the copending application recite "identifying a general area of a corresponding vessel". Examiner acknowledges that "localizing" and "identifying" are not exactly the same. However, since both of these features are disclosed in both applications, and since localizing a vessel in three-dimensional space constitutes identifying a general area of a corresponding vessel constitutes, it is respectfully submitted that the two applications are claiming common subject matter. Hence, it is respectfully submitted that the rejection is proper.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application.

See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968).

See also MPEP § 804.

Obviousness-Type Double Patenting

11. Claims 1, 3-8, 12, 14-19, 23, 25-28, 29, 31-36, 40, 41-46, 50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-8, 12, 14-19, 23, 25-28, 29, 31-36, 40, 41-46, 50, 51 of copending Application No. 09/243,870. Although the conflicting claims are not identical, they are not patentably distinct from each other.

In particular, as discussed above, the independent claims 1, 12, 23, 29, 40 have been amended to recite "an arterial circulatory network" whereas the corresponding claims in the copending application have been amended to recite "an arterial circulatory network for a cerebrum". Although the copending application recites modeling an arterial circulatory network specifically for a cerebrum, it is an obvious modification of an arterial circulatory network in general. That is to say, the only difference between the claims of the present application and that of the copending application is that the invention of the present application is applied to a specific type of

arterial circulatory network (i.e., for a cerebrum). Hence, the only difference between the two application is that the copending application is directed to a smaller subset of the present invention (i.e., arterial circulatory network for a cerebrum in a total arterial circulatory network) which is an obvious modification to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

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13. Claims 1, 3, 12, 14, 23, 25, 29, 31, 40, 41, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Charbel #1 or under 35 U.S.C. 102(e) as being anticipated by Kamm et al.

a. Charbel #1 (Poster Presentation: Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation), submitted by the applicant, teaches a computerized modeling/simulation system that takes a generalized model of an arterial circulatory network and modifying it for a specific patient until an optimal mode is determined as recited in the above-identified claims. (p. 113).

b. Kamm et al. (US Pat. No. 6,117,087) teaches a computerized modeling/simulation system that takes a general model of an arterial circulatory network and modifies the general model with specific parameters of a patient for a more accurate model/simulation specific for that patient as recited in the above-identified claims. (See at least col. 1, lns. 25-26, 36-47, 60-65; col. 2, lns. 4-6; col. 3, lns. 6-10, 35-37, 45-68; col. 4, lns. 1-6, 23-28; col. 8, lns. 49-50, 54-56; col. 9, lns. 10-11; col. 10, lns. 33-35, 49-54; col. 13, lns. 25-26).

14. Claims 1-3, 12-14, 23-25, 29-31, 40-41, 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Charbel #2.

Charbel #2 (Predictive Value of a Computerized Model of the Cerebral Circulation), submitted by the applicant, teaches modifying any of a baseline model used, including the Circle of Willis, with specific parameters of a patient to simulate various procedures to be used on the patient as recited in the above-identified claims. (p. 166, sec. 27).

15. Claims 2, 9-11, 13, 20-22, 24, 30, 37-39, 47-49 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. In particular, the present application names 5 inventors. The copending U.S. application 09/243,870 names 7 inventors. However, claims 2, 9-11, 13, 20-22, 24, 30, 37-39, 47-49 of the present application are the same as that of claims 2, 9-11, 13, 20-22, 24, 30, 37-39, 47-49 in the copending application as explained in the Double Patenting rejections made above.

In particular, claims 2, 9-11, 13, 20-22, 24, 30, 37-39, 47-49 of the present application and that of the copending application are directed to modeling the arterial circulatory network for a cerebrum. As explained above, the present application has 5 inventors whereas the copending application lists 7 inventors. Hence, it is not understood how two

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different inventive entities can claim to have invented the same invention.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 4-8, 15-19, 26-28, 32-36, 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over either **Charbel #1** or **Kamm et al.** in view of either **Karplus et al.** or **Foutrakis**.

Charbel #1 and Kamm et al. disclose a computerized modeling/simulation system as explained above. Although both references disclose that the parameters of the vessels are measured and used in the modeling/simulation, these measurements are not obtained by processing the image of the actual arterial vessel.

Karplus (Simulation and Visualization of the Fluid Flow Field in Aneurysms: A Virtual Environments Methodology), previously cited, discloses a method and system for performing virtual surgery to repair an aneurysm of blood vessel. More importantly, the system obtains vessel parameters such as cross-section dimensions by processing the image of an actual vessel including boundary identifications from the images (p. 37-38, §§ 3-3.2)

Foutrakis (Construction of 3-D Intracranial Arterial Meshes from Magnetic Resonance Angiography), previously cited, discloses a method and system for obtaining vessel specific

parameters by analyzing the images of a blood vessel obtained by MRI (Magnetic Resonance Imaging).

These two references are only examples that it is well known in the medical art to obtain vessel specific parameter using image processing. Hence, it would have been obvious for one with ordinary skill in the art to have obtained vessel specific parameters using image processing as taught by Karplus or Foutrakis to be used in the modeling/simulation system of Charbel #1 or Kamm et al. because image processing of vessels is advantageous in that it is non-invasive and faster to obtain such complicated sets of parameters using a computer to analyze a digitized version of the images.

18. Claims 9-11, 20-22, 37-39, 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Charbel #1 or Kamm et al. in view of either Karplus et al. or Foutrakis as applied to claims 4-8, 15-19, 26-28, 32-36, 42-46 above, and further in view of Charbel #2.

The combination of either Charbel #1 or Kamm et al. in view of either Karplus et al. or Foutrakis teaches the claimed invention as described above. However, the combination does not specifically teach that the analysis is a one-dimensional,

explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to the size of the artery.

Charbel #2, applied above, discloses that such an algorithm has been in use since 1994. Furthermore, various other references cited by the applicant in IDS (paper no. 7) teaches that such an algorithm is old and well known in the art (e.g., Imaeda et al., Segers et al., etc.) Hence, it would have been obvious for one with ordinary skill in the art at the time of the invention to have used the recited algorithm in the combination above because such an algorithm to model an arterial circulatory network was well known in the art and one with ordinary skill would have been motivated to use an algorithm that would return the most accurate result.

19. **Claims 4-11, 15-22, 26-28, 32-39, 42-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over either **Charbel #2** in view of either **Karplus et al.** or **Foutrakis**.

Charbel #2 disclose a computerized modeling/simulation system as explained above including using one-dimensional, explicit, finite-difference algorithm based on a conservation of

mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to the size of the artery. Although it discloses that the parameters of the vessels are measured and used in the modeling/simulation, these measurements are not obtained by processing the image of the actual arterial vessel.

Karplus and **Foutrakis** teach using image processing to obtain vessel specific parameters as explained above. Hence, it would have been obvious for one with ordinary skill in the art to have obtained vessel specific parameters using image processing as taught by **Karplus** or **Foutrakis** to be used in the modeling/simulation system of Charbel #2 because image processing of vessels is advantageous in that it is non-invasive and faster to obtain such complicated sets of parameters using a computer to analyze a digitized version of the images.

Response to Arguments

20. Applicant's arguments with respect to claims 1-50 have been considered but are moot in view of the new ground(s) of rejection based on the amendment received on February 1, 2001.

21. As to applicant's arguments regarding §102(f), it is true that the inventorship is presumed to be correct. However, as

with all presumptions, the burden of proof shifts to the applicant when sufficient facts arise that challenges such a presumption. Indeed, as stated in M.P.E.P. §706.02(g):

... The examiner must presume the applicants are the proper inventors unless there is proof that another made the invention and that applicant derived the invention from the true inventor. (emphasis added)

See also M.P.E.P. §§2137-2137.02

There is no provision in the statute (35 U.S.C.), rule (37 C.F.R.), or in the manual (M.P.E.P.) that bars an examiner from making a §102(f) rejection as asserted by the applicant's representative. On the contrary, §102(f) provision exists for the exact situation as this.

As explained in detail above, the scope of the claims in the two applications overlap. Two different inventive entities are claiming right to exactly the same invention. It is respectfully submitted that enough facts have been asserted to question who the actual inventors are for the claimed invention. It is the applicant's burden to prove who invented what (e.g., by either amend the claims to particularly point out and distinctly claim what the inventors regard as their invention or amend the inventive entities so that both applications have the same inventive entity).

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Kyle J. Choi** whose telephone number is (703)306-5845. The examiner can normally be reached on Monday-Friday, 8:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Tariq Hafiz** can be

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reached on (703)305-9643. The fax phone numbers for the organization where this application or proceeding is assigned is (703)308-6306 for regular and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-3900.

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to:

(703)308-6306 (informal or draft communications should be labeled "PROPOSED" or "DRAFT").

Hand delivered responses should be brought to Crystal Park 2, 2121 Crystal Drive, Arlington, VA., 4th floor receptionist.

KJC
April 23, 2001



TARIQ R. HAFIZ
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TECHNOLOGY CENTER 2100